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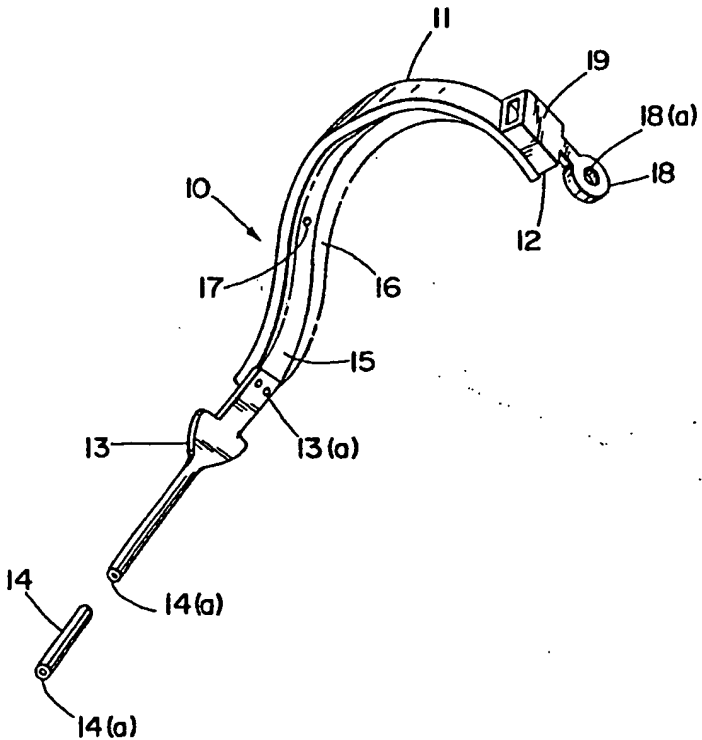
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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification ⁵ : A61B 17/04</p>	<p>A1</p>	<p>(11) International Publication Number: WO 94/27504 (43) International Publication Date: 8 December 1994 (08.12.94)</p>
<p>(21) International Application Number: PCT/US94/05814 (22) International Filing Date: 23 May 1994 (23.05.94) (30) Priority Data: 08/068,411 27 May 1993 (27.05.93) US (71) Applicant: INAMED DEVELOPMENT COMPANY [US/US]; 1035B Cindy Lane, Carpinteria, CA 93013 (US). (72) Inventor: VINCENT, Vermont, L.; 22 Pine Street, Santa Barbara, CA 93105 (US). (74) Agent: PETIT, Michael, G.; 510 Castillo Street, Santa Barbara, CA 93101 (US).</p>		<p>(81) Designated States: AU, CA, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i></p>
<p>(54) Title: UNIVERSAL GASTRIC BAND</p> <p>(57) Abstract</p> <p>A gastric band useful for the surgical treatment and control of morbid obesity. The gastric band (10) has inner and outer surfaces. The inner surface (15) has an inflatable member (16) disposed thereon which substantially completely covers the inner surface (15) of the band (11). The gastric band (10) is fastened in an encircling position around the stomach. After the band (10) is fastened around the stomach, a fluid is injected into the inflatable member (16) thereby constricting the stoma of the stomach. The inflatable member (16) is adjusted so that the stoma opening is at the desired diameter. The gastric band requires no adjustment other than inflation and presents a smooth, continuous inner surface to the adjacent tissue, thereby reducing necrosis.</p>  <p>The diagram illustrates a gastric band (10) in a curved, encircling position. It features an inner surface (15) and an outer surface (11). An inflatable member (16) is disposed on the inner surface (15). The band is fastened at one end by a clasp mechanism (12, 13, 13(a), 14, 14(a)) and at the other end by a connector (19). A tube (17) is attached to the inflatable member (16) for fluid injection. A small circular component (18, 18(a)) is also shown near the clasp mechanism.</p>		

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1 UNIVERSAL GASTRIC BAND

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3 BACKGROUND OF THE INVENTION4 1. Field of the Invention

5 This invention relates to devices for the control of obesity, and, more
6 particularly, to a surgically implantable adjustable band for encircling the stomach.

7 2. Prior Art

8 Several years ago, Kuzmak, et al. in U.S. Patent 4,592,339, incorporated
9 herein by reference, described a belt-like band for encircling the stomach to control morbid
10 obesity. The band comprised substantially a belt which could be passed around the stomach
11 in a circling position and then cinched tight in order to adjust the stoma opening within the
12 stomach. Further improvements in the gastric band have included having an adjustable
13 portion of the band comprising an inflatable member which permits the fine adjustment of
14 the stoma opening after the size of the stoma is initially set by the band tightening
15 procedure. The band tightening procedure normally involves the placement of a calibrating
16 apparatus in the stomach to detect the stoma size. Once the apparatus is placed within the
17 stomach the gastric band is cinched down tight until the stoma opening approximates the
18 desired size. The band is fastened in position, usually by sutures, and the stoma opening
19 finally adjusted by injecting a fluid into an inflatable member which is coextensive with a
20 portion of the inner stomach-contacting surface of the band. The means for injecting the
21 fluid into the inflatable member usually comprises a fill port located beneath the skin which
22 can be accessed extracorporeally by transdermal injection. Thus, following implantation,
23 the gastric band can be adjusted, within a narrow range, to enlarge or reduce the stoma as
24 required.

25 One of the disadvantages of the prior art gastric bands is the difficulty in
26 tensioning the band around the stomach to approximate the desired stoma. This is
27 particularly difficult when the band is to be placed laparoscopically. When the band is
28 placed laparoscopically, special instruments are required to tension the band prior to the fine
29 adjustment of the stoma. Such instruments as are required to grasp the band and pull it into

1 an encircling position around the stomach then cinch it tight, are difficult to manipulate
2 through a laparoscopic canula. It would therefore be desirable to provide a band having an
3 inflatable member thereon which can be easily fastened into an encircling position around
4 the stomach and in which the adjustment of the stoma opening can be regulated solely by
5 the injection of fluid into the inflatable member.

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SUMMARY OF THE INVENTION

8 An object of this invention is to provide a gastric band which can be
9 laparoscopically placed and non-adjustably fastened into an encircling position around the
10 stomach to form a ring having an inner diameter.

11 It is yet another object of this invention to provide a gastric band wherein the
12 band can be easily affixed in an encircling position around the stomach by conventional
13 laparoscopic instruments.

14 It is yet another object of this invention to provide a gastric band adapted for
15 laparoscopic placement around the stomach and thereafter to be non-adjustably locked into
16 a circle around the stomach to compress the encircled portion of the stomach to constrict
17 the stoma thereof which constriction may be further adjusted solely by means of an
18 inflatable member.

19 It is yet a further object of the invention to provide a gastric band having an
20 inflatable member deployed on an inner surface wherein said inner surface presents a
21 smooth, continuous surface when the band is fastened in an encircling position and the
22 inflatable member is inflated.

23 These and other objects of this invention will soon become apparent as we
24 turn now to the preferred embodiments.

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BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of the gastric band according to the present invention.

Figure 2 is the gastric band according to the present invention fastened in an encircling position and partially inflated.

DESCRIPTION OF THE PREFERRED EMBODIMENT

As mentioned earlier, prior art gastric bands have two steps or stages of adjustment: the first step roughly affixes the gastric band in a position to encircle the stomach with the stoma opening approximating the desired size. This first adjustment is analogous to tightening a belt around the waist until the buckle tongue passes through one of a plurality of holes rendering comfortable tension. The next step in the adjustment requires injection of a fluid into the inflatable member to bring the stoma opening to the desired size.

Prior art gastric bands, lacking a large range of inflatable adjustment, require an initial "rough" adjustment. The "rough" adjustment comprising the first step in the gastric stoma-constricting process requires tensioning the prior art band, and holding the tension on the band, while sutures are placed to lock the band in the encircling position. This is a cumbersome procedure to perform laparoscopically and the design of the present invention overcomes some of the difficulties with tensioning the band.

Turning now to Figure 1, we see a gastric band, generally indicated at the numeral 10, which has a body portion 11 with an inner stomach-facing surface 15. The body portion 11 has a head end 12 and a tail end 13 with one or more suture holes 13(a) therein. A fill tube 14, which is generally a tube having a single lumen 14(a) coextensive therewith, is in fluid communication with an inflatable member 16 on the inner surface 15 of the band body 11. It is an important feature of this invention that the inflatable portion 16 is substantially co-extensive with the inner surface 15 of the body portion 11 so as to present a substantially continuous surface free of abrupt contours when the band encircles the stomach and the inflatable portion 16 is inflated. The central lumen 14(a) of the fill tube 14

1 enters into the inflatable member 16 at lumen opening 17. The head 12 of the body portion
2 11 has a buckle 19 with a pull tab 18 having a suture hole 18(a) integral therewith. Both
3 portions which receive a suture, that is the pull tab 18 and the tail 13, are preferably medical
4 grade silicone reinforced with dacron.

5 In practice, the gastric band is placed in the circling position around the
6 stomach as shown in Figure 2. (In Figure 2 the stomach is omitted for clarity.) This is
7 accomplished by pushing the fill tube 14 through a laparoscopic canula (not shown) in the
8 patient's abdomen. Laparoscopic placement consists of blunt dissection around the greater
9 curvature of the stomach. The end of the fill tube 14 is passed around the stomach, and the
10 tail 13 is attached to the buckle 19, so that the buckle and the tail are non-adjustably and
11 irreversibly affixed to one another. In this sense, the band is a "one-size-fits-all" device.
12 That is, for a particular band there is only one single position in which the tail and buckle
13 can be attached to one another. Further adjustment of the stoma; the narrow opening in the
14 stomach created by the band, is performed solely by inflation or deflation of the inflatable
15 member 16 after the band is secured in this single position.

16 Prior art gastric bands employ an adjustable balloon portion used for small
17 post-operative adjustment of the stoma if necessary. The laparoscopic hydraulic gastric
18 band outlined herein has a larger balloon covering a greater area of the inner surface of the
19 gastric band than taught in the prior art. The inflatable member or balloon 16 preferably is
20 coextensive with the inner stomach-facing surface 15 of the band between the head end 12
21 and the tail end 13. This larger balloon 16 is utilized to adjust the stoma at the time of
22 surgery. The interior of the adjustable balloon 16 is in fluid communication with an
23 injection reservoir (not shown) by means of the central lumen 14(a) of the fill tube 14, as
24 with prior art adjustable gastric bands. The inflatable member 16 is gradually inflated with
25 saline via the injection reservoir (not shown) such that the inflatable member 16, which, as
26 stated above, is coextensive with the inner surface 15 of the band 11 between the head end
27 12 and the tail end 13, presses on and constricts the stomach wall underlying the band. This
28 results in the decrease of the opening (stoma) inside the stomach directly under the
29 encircling band. The continuous surface presented by the enlarged inflatable member to the

1 underlying tissue inhibits squeezing of the tissue into wrinkles, dimples or similar
2 discontinuities such as are present on the inner surface of prior art bands and thereby
3 prevents necrosis.

4 An electronic pressure transducer known as a gastrostemoneter electronic
5 sensor, coupled to a calibration probe known generically as a "calibration tube" is used to
6 measure the size of the stoma. The calibration tube is introduced through the patient's
7 mouth and esophagus into the stomach. The band is inflated, tightening it around the tip of
8 the calibration tube. The gastrostemoneter electronic sensor indicates the stoma diameter
9 created as the band is tightened.

10 The present invention allows for the laparoscopic implantation of a
11 therapeutic surgical device without the risks associated with major abdominal incisions in
12 the obese patient. Faster healing, reduced complications, reduced hospital stay and
13 drastically reduced pain are among the advantages of laparoscopic placement. The gastric
14 band according to the present invention facilitates laparoscopic placement and will also
15 allow wider use of the gastric band system to create a gastric restricter procedure for the
16 treatment of morbid obesity. This band enables more surgeons, skilled in the art of
17 laparoscopic surgery to undertake this operation without the need for highly specialized,
18 difficult to use tensioning instruments. Since there is only one single, non-adjustable
19 locking position for the band around the stomach, the procedure itself should lend itself to
20 more rigorous standardization. Also, more patients will consider having this procedure
21 performed because of the advantages of laparoscopic surgery over traditional abdominal
22 laparotomies. These advantages, coupled with the advantages of the prior art gastric bands,
23 which enable post operative fine tuning of the stoma, enable a more facile procedure to be
24 performed.

25 In general, the smoother or more continuous the inner surface 15 of the band
26 10, the less likely the chance of necrosis. The single locking or fastening position of the
27 present gastric band ensures that the inflatable member 16 will be substantially coextensive
28 with the inner surface 15 of the band 10 and continuous with the buckle 19. This fixed-
29 diameter band enables the inner surface 15 to present as a continuous surface to the

1 encircled tissue as the band is inflated, thereby preventing necrosis. Prior art gastric bands
2 lack a provision for assuring that the inflatable member is adjacent to and continuous with
3 the buckle portion when the band is locked into an encircling position. This permits a gap
4 or space between the inflatable member and the buckle along the inner surface when the
5 inflatable member is inflated. Tissue can squeeze into such a gap, causing necrosis. The
6 reduction and/or elimination of such discontinuities on the inner surface of the (inflated)
7 band as taught hereinabove reduces the possibility of necrosis.

8 While particular embodiments of the present invention have been illustrated
9 and described, it would be obvious to those skilled in the art that various other changes and
10 modifications can be made without departing from the spirit and scope of the invention. It
11 is therefore intended to cover in the appended claims all such changes and modifications
12 that are within the scope of this invention.

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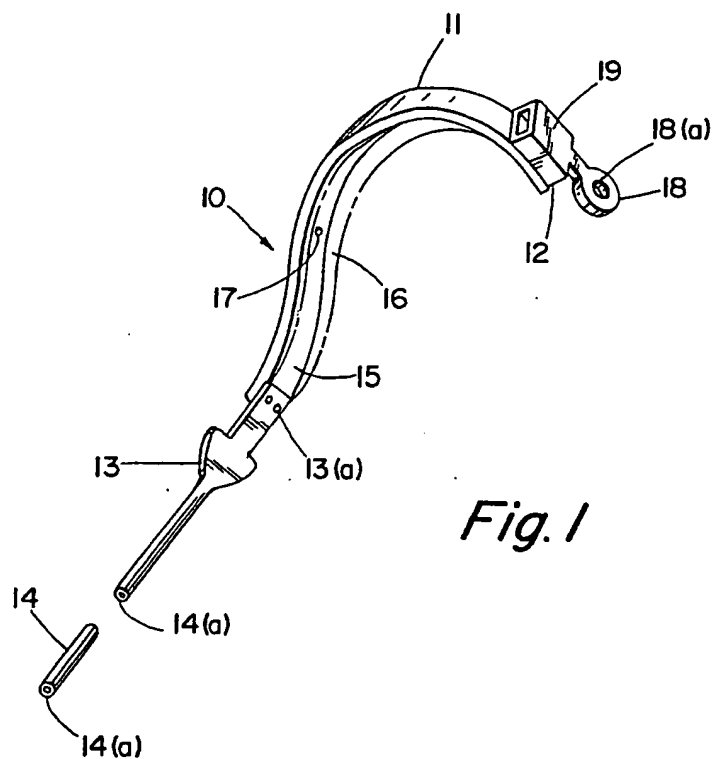
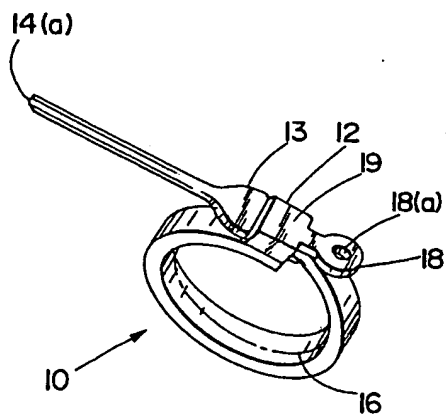
CLAIMS

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What I claim is:

1. In a gastric band adapted for laparoscopic placement around the stomach of a patient for the treatment of morbid obesity, said band comprising a body portion having a head end and a tail end and an inner surface therebetween, and wherein said tail end comprises an elongate tubular member having means thereon for providing a fluid-tight connection of said tubular member to an injection reservoir, and wherein said head end has locking means thereon for receiving said tail end and locking said band into a circle having an inner diameter, and wherein said gastric band has an inflatable member affixed to the inner surface which said inflatable member is in fluid communication with said tubular member, the improvement wherein said locking means is non-adjustable and wherein said inflatable member is substantially entirely co-extensive with said inner surface of said body portion of said gastric band when said band is non-adjustably locked into said circle having said inner diameter.

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*Fig. 1**Fig. 2*

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/05814

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) A61B 17/04

US CL :24/16PB, 17AP; 606/151, 216

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 24/16PB, 17AP; 606/151, 216

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONEElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)
NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 5,207,694, (BROOME), 04 May 1993. See entire document.	1
Y	US, A, 4,592,339, (KUZMAK ET AL.), 03 June 1986. See entire document.	1
A	US, A, 4,813,416. (POLLAK ET AL.), 21 March 1989. See entire document.	1

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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